This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

AMVAC

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May 4, 1999

Via Facsimile

Mr. Robert C. McNally
Special Review Branch Chief
Special Review and Reregistration Division
Office of Pesticide Programs
United States Environmental Protection Agency
Mail Code 7508W
401 M Street, S.W.
Washington, D.C. 20460

Re: DDVP Draft Preliminary Risk Assessment

Dear Bob:

Appended is a document entitled "Additional Information on DDVP" that Amvac Chemical Corporation offers to EPA in its preparation of the preliminary risk assessment for DDVP. Amvac is preparing an additional letter which it intends to submit tomorrow. As always, please call if you have any questions.

Sincerely,

Ian S. Chart

Attachment
cc: Marcia E. Mulkey, Esquire (w/attachment)
Mr. Jack E. Housenger (w/attachment)
Mr. Dennis Utterback (w/attachment)
Ms. Pam Noyes (w/attachment)

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ADDITIONAL INFORMATION ON DDVP

DISCUSSION ON THE NEED FOR AN ADDITIONAL ('FQPA') UNCERTAINTY FACTOR

1. INTRODUCTION

The toxicology data base for DDVP has been reviewed giving special reference to the reproductive, developmental and neurotoxicity data to address the concern of the sensitivity of infants and children from potential exposure to DDVP as required by the Food Quality Protection Act (FQPA) of 1996.

2. RESULTS

An evaluation of the toxicology database shows the following:

2.1. Neurotoxicity

The acute and subchronic neurotoxicity data show no apparent histopathological changes due to exposure to DDVP in rats and hens (Ghali, 1997). In addition, DDVP has shown no effects on neurotoxic esterase (NTE).

2.2. Developmental Toxicity

The developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity to young rats or rabbits following pre-and post-natal exposure to DDVP and comparable NOELs were established for adults and offspring.

2.2.1. In rats there have been at least 5 developmental studies performed.

2.2.2. In rabbits there have been 6 developmental studies performed.

2.2.3. In the guinea pig there has been one study reported (Mehl *et al.* 1994).

The additional information on the Mehl *et al.* paper has been submitted but is included here for ease of reference.

We learned several startling facts regarding the study conduct and the findings that directly impact the interpretation of the study.

a) The route of exposure to DDVP was subcutaneous. This was not mentioned in the publication.

b) The single animal that was dosed with 15 mg/kg of DDVP subcutaneous had clinical signs of cholinesterase toxicity including involuntary jaw movements and salivation. This pregnant dam, although clearly indicating signs of OP toxicity, had offspring that had normal brain development. The authors considered this dose to be a no effect level.

c) The pregnant dam dosed with 20 mg/kg of DDVP subcutaneously had signs of severe organophosphate toxicity. This animal was not studied further. More importantly, this information was not included in the publication. The authors did not offer a reason for deleting this critical information. These data establishes a

dose of 20 mg/kg as a near lethal dose. Therefore, the 15 mg/kg is certainly documented to be as high a dose as can be tested but no fetal effects were observed.

d) The 2 pregnant dams dosed with 30 mg/kg of DDVP had clear signs of cholinesterase poisoning. Data from these animals were pooled in the paper for analysis, however, the dose regime was different for each of these animals during the study.

e) The animals treated with DDVP were dosed on separate occasions over a period of several years but the data reported as if it was one experiment.

f) The study had no Quality Assurance, was not performed to GLP standards and laboratory records could not be located.

g) In light of this information, it is totally inappropriate to use this data as a basis for a regulatory decision. It is arbitrary for the Agency to request us to repeat a study when the limited findings are at near lethal range from an exposure route wholly inappropriate for a pesticide. In particular, the allocation of an additional "times 3" ('FQPA') factor is not defensible where no selective fetal toxicity is demonstrated.

Furthermore, it is noted that no such developmental studies in the guinea pig have ever been performed at commercial contract testing laboratories under GLP and there is no evidence from the extensive DDVP toxicology database that guinea pigs are more sensitive than other laboratory species that has been tested (e.g., rat rabbit or mouse).

2.3. Reproductive Toxicity

In the two generation reproduction study in rats, there was no evidence of enhanced susceptibility following pre and/or post natal exposure (i.e., effects noted in the offspring occurred at maternally toxic dose levels or higher).

2.3.1. Cholinesterase Inhibition

2.3.1.1. In a single generation reproduction study in rats (Tracy *et al.*,1960) female rats nursing litters were repeatedly dosed by oral administration of 30 mg DDVP/kg. The pregnant dams were dosed with sufficient DDVP to cause marked inhibition of plasma and RBC cholinesterase. The litters of these rats exhibited normal ChE levels in erythrocytes and plasma as well as normal weight curves.

2.3.1.2. Cholinesterase activity has been measured in many human and animal studies for both young and older age ranges (see Appendix 1).

3. Data Gaps

3.3. Toxicity

There are no outstanding data gaps for DDVP in the toxicity database, with respect to the standard Subdivision F Guideline requirements.

3.4. Exposure

An extensive exposure database for human subjects is available and is presented in Appendix 1.

HUMAN STUDIES MEASURING THE HEALTH EFFECTS OF REPEATED EXPOSURE TO DDVP VAPOR

There are eight significant studies that have measured the health effects from repeated exposure to DDVP vapors in humans. The repeated exposure studies were conducted for several different reasons. Studies by Funckes *et al.* (1963), Stein *et al.* (1966), and Gratz *et al.* (1963) were part of a large-scale project conducted by the World Health Organization to determine the suitability of using dichlorvos to eradicate malaria. The Leary *et al.* (1974) study consisted of 3 separate studies in Arizona that were conducted as part of the development and product stewardship effort on pest strips. The first study in this series was conducted for 12 months; the longest study conducted on the health effects of exposure to pest strips in the home. The second study spanned a six-month period. The last study, the Arizona III study, included an effort to push exposures far higher than would occur under use conditions but also to do extensive measurements on the dichlorvos content in food, as pest strips at that time were allowed in the kitchen and dining rooms. The study conducted at the Kettering Laboratory (1965) was a study of resin strips and their safety for home application. The Ottevanger (1975) study was conducted in the Netherlands with an effort to study the health effects from continuous exposure to pest strips used both in the home and at the office. This study specifically evaluated neurological and muscle function by conducting electromyographic tests on the subjects before, during, and after continuous exposure to pest strips. These studies are summarized below.

Studies Measuring the Health Effects of Repeated Exposure to Dichlorvos Vapors

STUDY	PURPOSE	POPULATION
Funckes *et al.* (1963)	Malaria Eradication	Families with children exposed in homes
Gratz *et al.* (1966)	Malaria Eradication	Families with children exposed in homes
Stein *et al.* (1963)	Malaria Eradication	Families with children exposed in homes
Leary *et al.* (1974) [3 separate studies]	Pest Strip Development	Families with children exposed in homes
Kettering Laboratory (1965)	Home Safety of Resin Strips	Adult families
Ottevanger (1975)	Pest Strip Safety and Product Stewardship	Male adult employees

The following is an in-depth evaluation of each of the studies. The strengths and weaknesses of the studies are discussed. Exposure methods and results are reviewed and summarized.

Funckes *et al.* (1963). Initial field studies in Upper Volta with dichlorvos residual fumigant as a malaria eradication technique. *Bull. Wld. Hlth. Org.* 29:243-246.

The entire village of Wakara in the Upper Volta was treated with DDVP in order to study its efficacy and safety for malaria control. The people of the village of Sara served as a control for health comparisons. There is a detailed description of the methods used and the general work plan for the project in separate publications by Quarterman *et al.* (1963) and Mathis *et al.* (1963). Physical health examinations and cholinesterase and hemoglobin levels were determined for all subjects before and after exposure. In addition, cholinesterase measurements were made at approximately 2-week intervals during the exposure portion of the study.

Subjects included a wide distribution of men, women, children, and infants. A relatively large population was studied and included subjects that were randomly selected as well as subjects that participated in more in-depth studies that were conducted to increase the levels of DDVP. The subjects are summarized below:

Subjects in the Funckes *et al.* (1963) Study Exposed to DDVP vapors

SUBJECTS & SELECTION METHOD		NUMBER	AGE, YEARS
Men, women, and children	Selected randomly from treated village	29	<6 to 64 males <6 to 51 females
Men, women, and children	Studied intensively	15	<6 to 43 males <6 to 37 females
Infants and children	Selected randomly from treated and untreated village	11 treated 9 controls	4 months to 5 yr 4 months to 5 yr

Analytical measurements were made from representative houses. Air concentrations were measured during the 50 days of exposure. The range, mean, and standard deviation were presented for three time periods for the two populations as shown in the following table:

Exposure Data from the Funckes *et al.* (1963) Study

SUBJECT	SOURCE	AIR CONCENTRATION (mg/m^3)	COMMENTS
29 men, women, and children	One DDVP dispenser per 400-1000 ft^3 (average of 500) for 50 days	Day 1-Day 10: Range: 0.007-0.059 Mean: 0.028 SD: 0.015 Day 11-37: Range: 0.008-0.147 Mean: 0.034 SD: 0.035 Day 38-Day 50: Range: 0.011-0.098 Mean: 0.052 SD: 0.031	This usage rate is greater than the maximum label rate; therefore, actual air concentrations are likely to be much less than those observed here.
15 men, women, and children	One DDVP dispenser per 60-88 ft^3 for 50 days	Day 1-Day 10: Range: 0.008-0.059 Mean: 0.022 SD: 0.012 Day 11-37: Range: 0.017-0.445 Mean: 0.134 SD: 0.103 Day 38 – Day 50 Range: 0.170-0.840 Mean: 0.433 SD: 0.237	Additional dispensers were placed in home up to 9 per one room home to result in higher air concentrations. This resulted in air concentrations which would not be found in typical use, particularly as changes in the label now prohibit the use of strips in certain areas.

Health evaluations did not show any effects attributed to dichlorvos exposure. In addition to the physical examinations, hematological and cholinesterase in RBC and plasma were measured. No effect on hemoglobin or hematocrit of the subject populations occurred at any exposure level tested. When the study population randomly selected from the village whose houses were treated with dichlorvos averaging 0.038 mg/m^3 (regardless of time) no effect on either RBC or plasma cholinesterase was apparent. When exposures were incrementally increased until the average exposures were 0.433 mg/m^3 (with a concentration as high as 0.84 mg/m^3), no effects on either RBC or plasma cholinesterase occurred. When very young children from the exposed village of Wakara were tested for cholinesterase activity in both RBC and plasma and the values compared to those of a similar very young population in a neighboring village (Sara) that was untreated, no differences were detected.

Study Strengths:
- Diverse population including men, women, children, and infants
- Exposure measurements reported in detail
- Exposure methods discussed in detail
- Range of exposures over more than 10-fold studied

Relatively high levels of exposure to DDVP studied
Subjects randomly selected from an even larger study population
Statistical analysis and variability reported
Pre-test data available

Limitations: Statistical variability, but not individual data reported
Exposure duration 7 weeks.

Conclusion: This study measured quite high levels of exposures over a 7 week period, where homes were continuously treated with DDVP. A very diverse population was studied including sensitive subpopulations (e.g., infants). No health effects or cholinesterase inhibition was detected.

Leary *et al.* (1974). Safety evaluation in the home of polyvinyl chloride resin strip containing dichlorvos (DDVP). *Arch. Environ. Health* 29:308-314.

The Leary study involved 26 homes in Arizona and was designed to support the safety of pest strips for use in the home. The publication covers 3 separate studies, which are summarized as follows:

3 Studies Conducted on the Safety of Pest Strips in the Home by Leary et al. (1974)

Study	Number of homes	Pest strip usage	Length of the study	Strip replacement	Measurements conducted
Arizona I	7	1 per 1000 ft^3*, 7.5 to 18 per home	12 months	Every 3 months	ChE, hematology, clinical records
Arizona II	16	1 per 1000 ft^3, 4 to 18 per home	6 months	Monthly	ChE, hematology, clinical records
Arizona III	4	1 per 1000 ft^3, then 1 per 500 ft^3 8 to 18 per home	41 days	Extra strips added to kitchen and dining room after one month	ChE, physical exams, food measurements

***Flea collars worn by the household dogs. Two families also treated their closets with pest strips.**

The 3 studies that are reported together in the publication by Leary *et al.* (1974), provide the most extensive data base on the health effects of pest strips in the home. Studies extended several months up to a full year. Residents included families, consisting of men, women, and children and their pets. In total, 34 adults and 55 youth participated in the studies. Because more children than adults were included, this study measures effects in adults and also in children, providing information on whether children were more susceptible than adults to the effects of chronic DDVP exposure. Residents were encouraged to note health problems and to seek medical attention in case of any difficulties. A description and dates of all illnesses were noted. Hematological and

cholinesterase measurements were made. Analytical measurements were made of the levels of dichlorvos in the homes.

In the Arizona II study, the number of pest strips used per home, from 4 up to 18, was magnified substantially over current use. In addition, the frequency of changing the strips was increased 4-fold over current label in this study.

In the last study, the Arizona III study, a detailed analysis of the levels of DDVP in food were made, to support a food tolerance, as pest strips were used at that time in the kitchen and dining room (Shell Chemical Company, 1970). In addition, detailed air measurements were reported in this document (Shell Chemical Company, 1970).

Detailed information on exposure levels is available for the Arizona III study (Shell Chemical Company, 1970) discussed in the Leary *et al.* (1974) article. The air concentrations decreased during the first twenty-eight days of use of the resin strips and then increased on Day 29 when additional strips were placed in the kitchen and dining room areas. The time-weighted average (TWA) air concentration for the first 28 days was 0.094 mg/m^3, while the TWA air concentration for the entire exposure period was 0.13 mg/m^3. The detailed exposure data from this study are presented in the following table.

Air Concentrations (mg/m^3) from the Arizona III Study

Day	Mean	Max
1	0.1175	0.15
2	0.115	0.17
3	0.12	0.17
4	0.13	0.18
6	0.105	0.16
7	0.125	0.18
10	0.0975	0.12
13	0.08	0.1
16	0.085	0.12
21	0.0875	0.12
28	0.075	0.11
29	0.14	0.22
30	0.16	0.2
31	0.12	0.16
32	0.145	0.16
34	0.1375	0.17
35	0.125	0.15
38	0.13	0.17
41	0.1025	0.15

Measurements of DDVP residues in food were conducted from duplicate meals. The additional incremental dose of DDVP from these meals was approximately 10% of the air dose.

Findings from the 3 studies by Leary *et al.* (1974) are included in the following table:

Leary *et al.* (1974) Study Findings

Study	Clinical Findings Attributed to DDVP	Hematology	Cholinesterase Inhibition	
			RBC	Plasma
Arizona I	None	No effect	No effect	No effect
Arizona II	None	No effect	No effect	Slightly inhibited
Arizona III	None	No effect	No effect	No effect

The results from these studies demonstrated the safety of pest strip use in the home under exaggerated use conditions. No clinical findings were attributed to DDVP. Hematology studies including determinations of hemoglobin concentration, hematocrit, WBC counts, reticulocyte counts and platelet counts were all normal and not affected from the exposures. During the Arizona I study ,which lasted a year, some residents reported on average staying in their homes, approximately twice as long as others. This afforded the opportunity of splitting the population and comparing the results from each group since one group should have twice the exposure as the other. No differences were found when the data were analyzed in this manner.

In the Arizona II studies, strips were installed at the maximum label rate permitted at that time, up to 18 per home, and strips were replaced monthly rather than every 4 months, which is the current labeled replacement rate. Strips were installed in all three studies in the kitchen, dining room and bedrooms, rooms now not permitted to have pest strips. This study was conducted during the summer months. No information is available on the resulting air concentrations. These combined parameters would greatly increase their exposure over current use. RBC cholinesterase was not affected by treatment. There was a slight decrease in plasma cholinesterase (15 to 30%) that was apparent after 1 month of exposure, but did not get worse with the next 5 months of exposure even though exposures were maintained at a high level through monthly changes in pest strips and continued use throughout all rooms of the house. Plasma cholinesterase inhibition is not increased with increasing exposure time. Steady state for plasma inhibition is achieved in one month or less (1 month is the first time point measured).

Because of the existence of all individual air and cholinesterase data, the Arizona III study (Shell Chemical Company, 1970) provides an excellent opportunity to carefully assess the safety of DDVP exposures. The daily air concentration calculated from the Arizona III data during the 41-day exposure period was 0.13 mg/m^3. However, the total dose estimates must be adjusted to reflect the additional dose from ingestion of food containing DDVP due to the use of pest strips in the kitchen and dining room during the study. Thus, the total dose is increased by 10% (the average incremental increase). The estimates shown in the table below can be compared to the Collins and DeVries (1973) data, which is the basis of EPA's current risk assessment. As shown, the daily dose from the Collins and DeVries study is approximately 10-fold lower. The Collins and DeVries data, which is considered to be an overestimate of current practices as multiple strips (3-4) were used in a home, including in the kitchen and dining area. If this data is

interpolated to current use practices of resin strips under labeled conditions (e.g., only one or two strips per home as they cannot be used in the kitchen, dining areas, and children's or the elderly's bedrooms), the daily dose expected would be considerably less than that estimated from the Collins and DeVries study. Thus, comparing the estimated daily dose from current use as shown in the table below, there is a considerable margin of safety between current use and the Arizona III study where no effects were seen on plasma and RBC cholinesterase.

Total Dose Estimates from DDVP Resin Strip Exposure

	Daily Air Concentration (mg/m^3)	Daily Dose[1] (mg/day)
Arizona III	0.13	1.4[2]
Collins and DeVries	0.015	0.15
Current Label Use	0.015	<0.1[3]

[1]Assuming 16 hours of exposure and a breathing rate of 15 m^3/day
[2]Includes an additional 10% from food
[3]This is based on removing strips from the dining room, kitchen, and children's bedrooms, as it is expected that only one or two strips would be used rather than the 3-4 strips used in the study.

Study Strengths:
Diverse population including men, women, and children
Study duration up to 12 months.
Exposure measurements reported in detail
Exposure methods discussed in detail
Exaggerated exposure conditions
Actual pest strips used in conventional homes
Health issues recorded
Hematology measured
Length of time in the homes recorded
Repeated measurements of plasma and RBC cholinesterase
Relatively high levels of exposure to DDVP studied
Statistical analysis and variability reported
Pre-test data available
Some individual data available (Arizona III)

Limitations:
Some of the individual data not available (Arizona I and II).

Conclusions: This series of 3 studies measures quite high levels of exposures from actual pest strips over a period up to a full year in homes continuously treated with DDVP. A very diverse population was studied including sensitive subpopulations (children). Typical homes were used. In all three studies, exaggerated exposure conditions involved using up to 18 strips per home. In all three studies, pest strips were used in the kitchen, dining room and children's bedrooms, rooms not permitted to be treated under current labeled use. In addition in one study, the Arizona II study, new pest strips were introduced monthly rather than every 4 months currently allowed. No adverse health effects were observed in any study. RBC cholinesterase was not affected in any study. Plasma cholinesterase was not

affected in 2 of the studies even though exposures in these studies were more than 10-fold higher than expected from current label usage and exposures were continued for an entire year.

In the Arizona II study only when exposures were additionally increased by replacing all strips every month throughout the homes, were slight effects on plasma cholinesterase apparent. This study demonstrates that steady state for plasma cholinesterase is achieved rapidly, within a couple of weeks. It also demonstrates that the margin of exposure is greater than 10 for residential pest strip usage.

Other Human Studies

There have been several other studies in which the health effects of chronic exposure to DDVP vapors have been evaluated in humans. These are studies which are more limited in nature than the extensive studies conducted by Funckes *et al.* (1963) and Leary *et al.* (1974). These studies serve to provide additional assurance of the safety for humans of chronic exposure to DDVP as the findings from these studies are consistent with those from other studies. Specifics regarding these additional studies are provided in the subsequent table.

Ottevanger, 1975

There has been concern that electromyographic alterations could in fact be more sensitive indicators of cholinesterase inhibitors. In order to determine if electromyographic evaluations would indicate any adverse effect from continuous exposure to DDVP vapors, this study made measurements before, during and after exposures for 3 months. Pest strips were hung at the maximum allowable in Europe at that time which are in excess of current label both in the home and at the office. Under these exaggerated conditions, no changes in the electromyographic evaluations or in blood cholinesterase was apparent. This study supports and confirms the results of Leary and also extends measurements when strips are also present at work.

Kettering Laboratory, 1965

This study measures both the potential health effect of handling the resin pest strips for 30 minutes each day and also measures the cholinesterase of adults living in homes that have been treated at levels in excess of current use. Strips were placed in each area of the home at a rate of 1 per 1000 ft^3, which is more than the current label which does not permit kitchen, dining room or small children's and the elderly's bedroom use. In addition strips were replaced monthly. The concentrations in the 2 surveyed residences were 0.087 mg/m^3 and 0.097 mg/m^3. Under these conditions, no effect on cholinesterase was noted in RBC or plasma. This study supports and confirms the work of Leary *et al.* (1974).

Gratz *et al.*, 1963

This study measured the effects of exposure of DDVP vapors on a village population. Exposures were continuous inside the home for 7 weeks. Both plasma and RBC cholinesterase was measured in a relatively large group of exposed individuals. Comparisons were made both to pretest values but also 30 controls from an untreated village. No effects on plasma or RBC cholinesterase were noted. This study is consistent with the results from the Funckes study and supports the results from the Ottevanger, Leary and Kettering study.

Stein *et al.*, 1966

This study focused on a group of occupationally exposed individuals that were both preparing and installing DDVP resin strips in homes. Protective clothing was not worn and rubber gloves had DDVP wax adhered to them, providing additional exposure. Air levels measured during the operation involved in preparing new DDVP resin strip generators indicated that exposure levels were extremely high (up to 2.13 mg/m^3). Levels were approximately 140 times those associated with current pest strip usage (0.015 mg/m^3). RBC cholinesterase was not affected by treatment. Plasma cholinesterase was moderately affected. From the reported results under conditions that were two orders of magnitude higher than expected from current use of pest strips, one can draw several important conclusions regarding exposure to DDVP in humans.

1. RBC is not affected by exposures even to extremely high levels.
2. Plasma cholinesterase can be affected, but the effect, even at these extremely high exposures is not severe.
3. Plasma cholinesterase inhibition reaches steady state quickly (within 1 to 2 weeks). Even with continued exposure, plasma inhibition is not further affected.
4. No symptoms were associated with exposure to DDVP vapor.

These findings confirm those reported in the Leary study where high exposures to DDVP did not affect RBC cholinesterase.

Conclusions from the Human Studies of Chronic Inhalation Exposure to DDVP

There are ample human data on which to set a NOAEL for chronic inhalation exposure to DDVP. Of the 8 studies, most demonstrated no effect on any parameter. In both the Arizona II study where exposures were increased substantially over those currently measured from current use of pest strips, and the study of occupationally exposed individuals in the study by Stein *et al* (1966) no adverse health effects have been associated with even high levels of DDVP exposure. RBC cholinesterase has not been reported to be affected from chronic exposures in any of the eight studies. Plasma cholinesterase is only affected when exposure conditions are severe and greatly in excess of those currently expected.

The best study on which to set the NOAEL for chronic inhalation exposure is the study by Funckes *et al.* (1963). This study evaluated exposures up to 0.433 mg/m^3. It also included evaluations of men, women, and very young children, thus affording an extra margin of safety. From other studies in which extremely high exposures occurred, it is known that plasma cholinesterase, if affected, reaches steady state for maximum inhibition within 1 to 2 weeks of exposure. The Funckes *et al.* study did not measure any decrease in plasma cholinesterase after 7 weeks of exposure, even in young children. Therefore, this study is of sufficient duration to be useful and acceptable to establish a NOAEL for chronic DDVP exposures via inhalation.

Additional Human Studies Determining the Health Effects of Repeated Exposure to DDVP Vapor

Study	Purpose	Design	Exposure	Population	Findings
Ottevanger 1975	Electromyography	Pest strips installed at rate of 1 per 30 m^2 in the office and at home	Continuous to the vapors from pest strips for 3 months	13 Adult men in good health (Netherlands)	No effect on EMG, no effect on blood ChE,
Gratz 1963	Malaria eradication	Vapor from solid and liquid DDVP dispensers inside homes.	Continuous inside huts for 7 weeks	Approximately 60 from population exposed in a village and 30 controls (Nigeria)	No effect on RBC or plasma ChE compared either to pretest values or a control village. No effect on hematocrit or hemaglobin
Stein 1966	Handling of DDVP dispensers used for malaria eradication,	Workers preparing & changing solid and liquid DDVP dispensers with rubber gloves and no special protection	Up to 6 weeks during work. Very high air levels (up to 2.13 mg/m^3) & skin contact.	18 working men, ave. age 32 years old, not in good health (Haiti)	No effect on RBC ChE. Plasma ChE depressed more in workers preparing dispensers. Maximal depression in 1-2 weeks.
Kettering 1965	Chronic vapor exposure	A) Resin pest strip handling. B &C) Resin pest strips inside homes at a rate of 1 per 1000 ft^3. Strips replaced monthly.	Severe continuous use inside of homes. Levels approximately 0.095 mg/m^3.	A) 10 adults (6 men, 4 women) handling vaporizers 30 min/day B) 2 men, 2 women living in 2 homes for 6 months. C) 6 Additional families for 2 months	A) No effect on plasma or RBC ChE B) No effect on plasma or RBC ChE C) No effect on plasma or RBC ChE

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Selection of the Best Study to Serve as the Basis for the Repeat Inhalation Risk Assessment of Dichlorvos

Study Type	Animal Study	Human Studies	
Study	Blair *et al.* 1974	Funckes *et al.*, 1963	Leary *et al.*, 1974
[illegible]	[illegible] report & publication	WHO Study	Shell Chemical Co report & publi[illegible]
Purpose	Carcinogenicity	Cholinesterase Effects and health observations	Cholinesterase Effects/health observations & food exposures
[illegible]	[illegible]	Humans	
Population Tested	Carworth farm E strain	Men, women and children	
[illegible]	[illegible]	[illegible] months to 64 years	[illegible]
Number Tested	8 to 24	19 selected randomly 25 additional 11 other children (ave. 23 mo.)	7 adults and 11 children
[illegible]	Vapor	Vapor	Vapor
DDVP source	Vapor generator	Vapor from solid source	8 to 18 Pest strips per home
[illegible]	[illegible]	[illegible]	Food exposures exaggerated with pest strips [illegible]
Setting	Chambers	Homes in Africa kept closed all evening and at night	Homes in Arizona kept closed
[illegible]	[illegible] hours/day	Continuously inside home	Continuously inside home
Days per week	7	7	7
[illegible]	[illegible]	[illegible] weeks	44 days
ChE Determinations	1	1 to 4 each	3 prior to exposure 13 during exposure
[illegible]	[illegible]	Compared to [illegible]	
NOAEL	0.05 mg/M[3]	0.43 mg/m[3]	
[illegible]	[illegible]	1) Other WHO studies 2) Kettering Lab 3) [illegible]	
Uncertainty	High	Low to Medium	
[illegible]	Difficult	[illegible]	

1) Blair D. *et al.* 2 year Inhalation Carcinogenesis Study in Rats. *Arch. Toxicol* 35, 281-294 1976.
2) Funckes AJ *et al.* Initial Field Studies in Upper Volta with Dichlorvos Residual Fumigant as a Malaria Eradication Technique. *Bull Wld Hlth Org.* 29, 243-246, 1963.
3) Leary JS *et al.*. Safety Evaluation in the Home of Polyvinyl Chloride Resin Strip Containing Dichlorvos (DDVP). *Arch Environ Health* 29, 308 – 314, 1974.

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APPENDIX 1

Robustness of Exposure Database from Use of DDVP Resin Strips

There have been numerous studies conducted to assess exposure to humans from the use of DDVP resin strips (also called "No-Pest Strips"). Many of these studies have been published in the scientific literature (i.e., Leary *et al.* 1974; Cavagna *et al.* 1969; Funckes *et al.* 1963). The studies are not only of healthy males, as typically seen in occupational exposure studies, but include human exposure data on sensitive subpopulations including infants and children, the elderly, and sick adults, children, and infants. These studies contain measurements of DDVP vapors and also measurements of plasma and RBC cholinesterase, hematocrit and hemoglobin levels, and assessments of clinical signs. There are few registered pesticides which have as complete a database, particularly for sensitive subpopulations. The following table presents a summary of some of the studies included within this database, however, additional studies are listed on the following reference list.

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SUMMARY OF DDVP CONCENTRATIONS IN AIR FROM USE OF PEST STRIPS

Location	Country	Dose	Ventilation	Time after placement	Ave Air Conc (mg/m^3) (range)	Max Air Conc (mg/m^3) (range)	Reference	Comments
House 123 rooms	UK	1 strip/30 m^3	Normal	1 week 1 month 3 months	0.03-0.06 0.02-0.04 <0.01-0.02		Elgar and Steer, 1972	30 rooms had 6.5 inch strips, however concentrations were comparable; maximums read from graph
House 20 rooms	S. France (summer)	1 strip/30 m^3 (10 inch strip)	Normal	Initial 4 months	0.03 0.01		Elgar and Steer, 1972	maximums read from graph
House 20 rooms	S. France (autumn)	1 strip/30 m^3 (10 inch strip)	Normal	First week 9 weeks 13 weeks	0.05 0.05 0.01		Elgar and Steer, 1972	maximums read from graph
House 12 rooms	Australia, Melbourne	1 strip/30 m^3 (10 inch strip)	Normal	First week 6 weeks 11 weeks	0.02 0.04 0.01		Elgar and Steer, 1972	maximums read from graph
House 27 rooms	Australia, Brisbane	1 strip/30 m^3 (10 inch strip)	Normal	1 week 3 weeks 4 weeks	0.02 <0.01 0.005		Elgar and Steer, 1972	maximums read from graph
House 5 homes	USA Modesto, CA	1 strip/28 m^3	Central air	1 day 7 days 14 days	0.05 (0.01-0.08) 0.05 (0.01-0.09) 0.04	0.08 0.09 0.07	Collins and DeVries, 1973	

Location	Country	Dose	Ventilation	Time after placement	Ave Air Conc (mg/m^3) (range)	Max Air Conc (mg/m^3) (range)	Reference	Comments
					(0.01-0.07)			
				28 days	0.02	0.05		
					(<0.01-0.05)			
				56 days	0.01	0.02		
					(<0.01-0.02)			
House	USA	1 strip/28 m^3	Wall or	1 day	0.06	0.11	Collins and	
5 homes	Modesto,		window		(0.02-0.11)		DeVries, 1973	
	CA		air	7 days	0.04	0.08		
					(0.02-0.08)			
				14 days	0.03	0.06		
					(0.02-0.06)			
				28 days	0.02	0.04		
					(<0.01-0.04)			
				56 days	0.01	0.04		
					(<0.01-0.04)			
House	USA	1 strip/28 m^3	No air	1 day	0.05	0.11	Collins and	
5 homes	Modesto,		conditioni		(0.02-0.11)		DeVries, 1973	
	CA		ng	7 days	0.04	0.07		
					(0.02-0.07)			
				14 days	0.02	0.02		
					(0.01-0.02)			
				28 days	0.02	0.03		
					(<0.01-0.03)			
				56 days	<0.01	0.01		
					(<0.01-0.01)			
House	USA	1 strip/28m^3	Minimal	1	0.1175	0.15	Leary *et al.*,	Concentrations taken
4 homes	Arizona			2	0.115	0.17	1974	from kitchen (8-18 strips
				3	0.12	0.17		per home); the strips were
				4	0.13	0.18		doubled in the kitchen
				6	0.105	0.16		and dining room at Day

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Location	Country	Dose	Ventilation	Time after placement	Ave Air Conc (mg/m^3) (range)	Max Air Conc (mg/m^3) (range)	Reference	Comments
				7	0.125	0.18		29 to increase residues in food. Food measurements were made. Dose from food is comparable to approximately 10% of air dose
				10	0.0975	0.12		
				13	0.08	0.1		
				16	0.085	0.12		
				21	0.0875	0.12		
				28	0.075	0.11		
				29	0.14	0.22		
		2 strips/28 m^3		30	0.16	0.2		
				31	0.12	0.16		
				32	0.145	0.16		
				34	0.1375	0.17		
				35	0.125	0.15		
				38	0.13	0.17		
				41	0.1025	0.15		
Hospital ward	Italy (winter)	1 strip/30 m^3	Minimal	2 days	0.15		Cavagna *et al.* 1969; Cavagna and Vigliani, 1970	Data from Shell 1989 – Cavagna and Vigliani in Italian – these concentrations are not available in this specificity from Cavagna *et al.*, 1969
				4 days	0.28			
				14 days	0.1			
				40 days	0.05			
				50 days	0.02			
Hospital ward	Italy (summer)	1 strip/30 m^3	High	2 days	0.05		Cavagna *et al.* 1969; Cavagna and Vigliani, 1970	Data from Shell 1989 – Cavagna and Vigliani in Italian – these concentrations are not available in this specificity from Cavagna *et al.*, 1969
				4 days	0.18			
				10 days	0.10			
				22 days	0.02			
Nursery	Italy (summer)	1 strip/40 m^3	Minimal with	2 days	0.13		Cavagna *et al.*, 1970	Newborn babies exposed; concentrations from
				5 days	0.09			

Location	Country	Dose	Ventilation	Time after placement	Ave Air Conc (mg/m^3) (range)	Max Air Conc (mg/m^3) (range)	Reference	Comments
			auxiliary ventilation	8 days	0.04			graph – two samples taken at each point
Nursery	Italy (summer)	1 strip/30 m^3	Low	2 days 2-5 days	0.18-0.25 0.11-0.28		Cavagna *et al.*, 1970	Newborn babies exposed; concentrations from graph – two samples taken at each point
Homes and offices	UK	1 strip/30 m^3	Normal	NA	Not given		Ottevanger, 1975	
Homes	Upper Volta	One DDVP dispenser per 400-1000 ft^3 (average of 500) for 50 days	Normal	Day 1-10 Day 11-37 Day 38-50	0.028 (0.007-0.059) 0.034 (0.008-0.147) 0.052 (0.011-0.098)	0.059 0.147 0.098	Funckes *et al.*, 1963	Malaria control
Homes	Upper Volta	One DDVP dispenser per 400-1000 ft^3 (average of 500) for 50 days	Normal	Day 1-10 Day 11-37 Day 38-50	0.022 (0.008-0.059) 0.134 (0.017-0.445) 0.433 (0.170-0.840)	0.059 0.445 0.840	Funckes *et al.*, 1963	Malaria control; additional dispensers were placed in home to result in higher air concentrations
Foodshop 37 shops	UK S. France	1 strip/45 m^3 2 strips/45-75 m^3 3 strips/75-105 m^3		2-7 days 4 weeks 6 weeks	0.03 (0.01-0.09) 0.02 (<0.01-0.07) 0.01	0.09 0.07 0.04	Elgar *et al.*, 1972	

Location	Country	Dose	Ventilation	Time after placement	Ave Air Conc (mg/m^3) (range)	Max Air Conc (mg/m^3) (range)	Reference	Comments
				10 weeks	(<0.01-0.04) <0.01 (<0.01-0.03)	0.03		
Restaurant 4 restrnts	USA, New York	1 strip/28 m^3		1 day 1 week 2 weeks 3 weeks 4 weeks	0.037 0.02 0.015 0.013 0.011		Anonymus, 1965	Information from Shell 1989
Simulated roof space 1 site	UK	1 strip/41 m^3	Twice normal	1 week 2 weeks 3 weeks 4 weeks 5 weeks 6 weeks 7 weeks 8 weeks 9 weeks 10 weeks 11 weeks 12 weeks	0.006 0.105 0.055 0.02 0.14 0.02 0.03 0.03 0.05 0.01 0.01 0.02		Harris *et al.*, 1970	Purpose of study was determine DDVP levels necessary for control of furniture beetles; Concentrations estimated from a graph
Sitting room 1 site	UK	1 strip/41 m^3	Normal	2 weeks 3 weeks 4 weeks 5 weeks 6 weeks 7 weeks 8 weeks 9 weeks 10 weeks 11 weeks	0.025 0.005 0.01 0.01 0.02 0.02 0.02 0.015 0.01 0.01		Harris *et al.*, 1970	Purpose of study was determine DDVP levels necessary for control of furniture beetles; Concentrations estimated from a graph

Location	Country	Dose	Ventilation	Time after placement	Ave Air Conc (mg/m^3) (range)	Max Air Conc (mg/m^3) (range)	Reference	Comments
				12 weeks	0.015			
Lined loft 5 sites	UK	1 strip/27 m^3	Minimal	1 week 2 weeks 3 weeks 4 weeks 5 weeks 6 weeks 7 weeks 8 weeks 9 weeks 10 weeks 11 weeks 12 weeks 13 weeks	(0.02-0.03) (0.04-0.1175) (0.01-0.04) (0.025-0.06) (0.01-0.15) (0.01-0.145) (0.03-0.12) (0.0225-0.14) (0.01-0.0225) (0.01-0.06) (0.01-0.0225) (0.01-0.015) (0.009-0.015)	0.03 0.1175 0.04 0.06 0.15 0.145 0.12 0.14 0.0225 0.06 0.0225 0.015 0.015	Harris *et al.*, 1970	Purpose of study was determine DDVP levels necessary for control of furniture beetles; Concentrations estimated from a graph
Unlined loft 5 sites	UK	1 strip/30 m^3	Minimal	1 week 2 weeks 3 weeks 4 weeks 5 weeks 6 weeks 7 weeks 8 weeks	(0.009-0.01) (0.009-0.04) (0.009-0.01) (0.009-0.015) (0.009-0.015) 0.009-0.01) (0.01-0.015) (0.009-0.025)		Harris *et al.*, 1970	Purpose of study was determine DDVP levels necessary for control of furniture beetles; Concentrations estimated from a graph

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